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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NAMJOO SUK, AS ADMINISTRATIX OF THE ESTATE OF STEPHEN A. SUK, AND NAMJOO SUK, INDIVIDUALLY, Plaintiffs vs. BIOPORT, INC., MICHIGAN BIOLOGIC PRODUCTS INSTITUTE, MICHIGAN DEPARTMENT OF PUBLIC HEALTH, JOHN DOES (FICTITIOUS NAMES, Nos. 1 – 50), Defendants.	Civil Action No.: Civil Action 03cv260 (DMC) **COMPLAINT AND JURY DEMAND** 1:04CV0218

THE PLAINTIFF, NAMJOO SUK, as administratrix of the Estate of Stephen A. Suk, and NAMJOO SUK, individually, by way of Complaint, truly and verily says:

STATEMENT OF JURISDICTION AND VENUE

1. This Court's jurisdiction is based upon diversity of citizenship, under 28 U.S.C. § 1332. Plaintiffs are citizens of New Jersey and the Defendants are all corporations duly authorized to do business in, and have its principal place of business located, in the State of Michigan. Complete diversity exists. The amount in controversy for each individual plaintiff is in excess of ($100,000.00)

2. Venue is laid in the District of New Jersey, as the Plaintiff resides within this District.

STATEMENT OF THE PARTIES

3. Plaintiff, NAMJOO SUK and decedent, STEPHEN A. SUK, were husband and wife and citizens of the State of New Jersey with an address of 477 Third Street, Palisades Park, New Jersey 07650.

4. The Defendant, BIOPORT, INC. (BIOPORT), a Michigan corporation with its principal place of business located at 3500 Martin Luther King Jr. Boulevard, Lansing, Michigan, 48906, is currently the sole manufacturer, designer, distributor, producer and seller of Anthrax Vaccine Absorbed ("AVA") under an exclusive contract with the United States Department of Defense ("DOD"). BIOPORT has assumed all liabilities of the Defendant, Michigan Biologic Products Institute ("MBPI") and the Michigan Department of Public Health ("MBPH"), and its successor corporation to MDPI and the Michigan Department of Public Health ("MDPH").

5. Defendant, Michigan Department of Public Health ("MDPH") through its biologic products division, is a resident of the State of Michigan with its principal place of business located at Louis Case Building, 6th Floor, 320 S. Walnut Street, Lansing, Michigan 48906. Both MBPI and BIOPORT were engaged in a private enterprise in which they were involved in the manufacturing, designing, distributing, producing and selling AVA from 1970 to 1995 and were indemnified by policies of insurance and/or by the Federal Government.

6. MBPI, a corporation duly licensed in the State of Michigan, with its principal place of business located at Louis Case Building, 6th Floor, 320 South Walnut Street, Lansing, Michigan 48906, was the immediate predecessor to BIOPORT, and was an autonomous,

temporary, 2-year agency created by Executive Order 1995-25 removing the biological products division from MDPH. MBPI continued the private enterprise at MDPH as it continued to manufacture, design, distribute, produce and sell AVA until it was sold to BIOPORT in 1998. MBPI was also indemnified by policies of insurance and by the Federal Government.

BACKGROUND AND FACTUAL ALLEGATIONS

7. In or about 1970, the United States Public Health Service issued the AVA license to the State-owned facility operated by the MDPH for protection against cutaneous Anthrax only. Prior to the issuance of the license, there had been no appropriate clinical trials of AVA. MDPH was the only entity with the capability and license to produce the Anthrax Vaccine.

8. In 1973, MDPH developed the biological product review information for AVA. In or about 1988, the DOD awarded MDPH a contract for 300,000 doses of Anthrax vaccine at a total cost of $2,789,325.00. Distribution took place from October 1988 through September 1994. The Anthrax vaccine was an off-the-shelf item already in production.

9. Prior to entering into the 1988 contract, the MDPH requested indemnification from DOD and was to comply with Section 15 of the "notice of claimed investigational exemption for a new drug" as published in 21 CFR 312.1. Pursuant to the contract, MDPH had to abide by the criteria and requirements of 21CFR 620.20.

10. In September, 1990, November, 1990, and February 1991 the DOD and MDPH amended the anthrax vaccine contract.

11. In 1991, the DOD and MDPH amended the contract again. This contract included payments of $525,000 for insurance coverage.

12. In or about September of 1991, the DOD awarded MDPH another contract for the purchase of additional quantities of the vaccine. This contract provided for additional insurance payments in the amount of $100,000 and general liability in the amount of $500,00 per occurrence. There were no specifications provided to BIOPORT by the DOD.

13. Pursuant to the 1991 amendments, the MDPH was still responsible for, among other things, producing, testing and storing the Anthrax vaccine according to MDPH's summary of procedures and proposals and meeting specifications of the product described in the product license application.

14. MDPH also promised to comply with the Good Laboratory and Manufacturing Practices with the regulations of the Federal Food Drug and Cosmetic Act, and with all other applicable Federal, State and local statutes, ordinances and regulations. Prior to entering into the 1991 contract, the DOD warned MDPH concerning insurance liability to third persons. In or about 1991, the DOD acknowledged that the government contractor defense is inapplicable because the vaccines are not made to detailed government specifications, i.e., "the government specification defense may not be applicable since the government does not actually design and control the production of vaccines".

15. In or about November 26, 1991, the Pentagon's deliberative process of mass vaccination of military personnel with AVA began with the development and implementation of DOD's directive 6205.3, DOD immunization program for biological warfare defense.

16. In or about 1997, MBPI no longer fulfilled the State government function and had become a self-sustaining enterprise with gross annual sales in the range of $75,000,000.00 per year.

17. In or about December 15 of 1997, Secretary of Defense William Cullen announced the Anthrax vaccination immunization program (AVIP) for all U.S. military personnel.

18. That the AVIP that began in December, 1997 intended to immunize over 2.4 million members of the military against hypothetical threats of weapon-grade inhalation Anthrax as a biological weapon.

19. The program required that between 1997 and 2003, all military personnel, including all new recruits, would begin an inoculation program in which they would receive a 6-shot series of Anthrax vaccinations.

20. In or abut July 8 of 1998, BIOPORT purchased substantially all of the assets of MBPI and assumed all of MBPI's liabilities.

21. BIOPORT became the sole licensed producer of AVA in the United States by way of privatization process initiated by the State of Michigan.

22. The DOD did not conduct any testing of the Anthrax vaccine. BIOPORT, MBPI conducted all of the testing as they were required to do by contract.

23. The Defendants were aware that the inoculations were non-voluntary and any soldier who refused inoculation was disciplined.

24. No soldier was informed of the risks of AVA, or that AVA was unlicensed for use to prevent inhalation Anthrax and no animal studies or human clinical trials demonstrated either safety or efficiency of the vaccine.

25. Defendants submitted false statements, records and claims for payment to the United

States in connection with the development and procurement of AVA for use by the DOD. The Defendant's false claims followed from false statements and false records provided by BIOPORT, Myers, MDPH and MDPI during several contracts between BIOPORT and the DOD from 1988 to the present.

26. AVA is a biological product as defined by 42 USC § 262(i). The Federal Food, Drug and Cosmetic Act 21 USC § 301 applies to biological products subject to regulation under 42 USC Section 262. The provisions promulgate the requirements for manufacture, storage, packaging and labeling, etc. of biological products.

27. The defendants violated 21 CFR Part 6012 that requires the FDA to be informed of each and every change in a product, production process, quality control, equipment, facilities, responsible personnel or labeling established in an approved license.

28. The plaintiff was inoculated with AVA.

FIRST COUNT [NEGLIGENCE]

29. Plaintiff hereby incorporates all of the above paragraphs as if each were set forth in full herein.

30. Defendants were careless, negligent and breached its duties and obligations to the Plaintiff and are strictly liable in tort for causing these injuries to the Plaintiff by negligently designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product in a defective condition which was unreasonably dangerous to the user; which was not safe for the normal handling and consumption by the user, and failing to have adequate warning on the product, failing to provide adequate warnings, failing to provide instructions to be followed with regard to

the use of the product; failing to warn users of the dangers inherent in using this product; failing to instruct users of this product on its safe use; failing to design, manufacture, produce, assemble, service, maintain, distribute, deliver, sell and/or supply a product which could have been designed more safely; in designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering and selling the product which lacked all necessary safety features to protect the users of said product; failing to have proper warnings and instructions concerning the use of the product, and in designing, manufacturing, producing, assembling, servicing and selling a product wherein it was foreseeable that someone would injure themselves based on the product's design and assembly and knowing that said product would not be safe during normal use and that said product was not safe for its intended use; and selling, manufacturing, designing and producing a product which is defective and which would cause injury to the end user; failing to exercise reasonable care in the design of the product; failing to properly test the product; failing to use reasonable care under the circumstances; in the designing, manufacturing, producing and assembling a product which the defendant knew or should have known would cause injury to the user; failing to fix the condition which increased the risk of harm to the users during the time which the product was serviced; and as a result of the carelessness and negligence of the defendants and their failure to conform it, its obligations and duties as designers, manufacturers, producers, assemblers, distributors, suppliers, installers, servicers and sellers, the Plaintiff was caused to suffer extreme pain and suffering, including death, and that the Plaintiffs incurred medical care and treatment and/or other financial expenses or losses for their great detriment and expense, including pain and suffering, pecuniary losses, loss of services and loss and support of guidance to

their children as a result of the negligence as hereinbefore alleged and as a result of the delivery of AVA inoculation.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and/or individually, for a sum of money in excess of $100,000.00 as compensatory damages, punitive damages, attorneys fees, interest, costs, and other such relief as the Court may deem to be necessary, in the interest of justice.

SECOND COUNT - [BREACH OF WARRANTY]

31. Plaintiff hereby incorporates all of the above paragraphs as if each were set forth in full herein.

32. Defendant breached their express and implied warranties that AVA designed, assembled, installed, produced, distributed, supplied, delivered, serviced and sold by them were safe and proper for its intended use, was designed and manufactured in accordance with prevailing and existing standards in the industry, and which properly and adequately manufactured, designed,. maintained, prepared, produced, distributed, sold, installed, and has proper warnings.

33. The defendant breached their express and implied warranties by designing, manufacturing, producing, servicing, assembling, distributing, delivering, installing, supplying and selling AVA which was unsafe, defective, of non-merchantable quality, and was not reasonably safe for its intended purpose or use.

34. Defendant breached their express and implied warranties, duties and obligations and thereby caused injury to the plaintiff and did so by failing to properly design,

manufacture, produce, assemble, service, maintain, distribute, deliver and sell and supply the product in a defective condition, design and manufacture, produce, assemble, service, maintain, distribute and deliver a product which was unreasonably dangerous to the user, not safe for normal handling and consumption, failed to have adequate warning, failed to provide a proper instruction, failed to warn the user of the dangers of use of said product; failed to instruct the user in the use of said product, and failed to design a product which could have been designed more safely and failed to take all necessary steps to protect the user of said product; as a result the defendants breached their implied and express warranties and the Plaintiff was caused to experience great pain and suffering, continues to experience great pain and suffering, and ultimately caused the death of plaintiff, STEPHEN A. SUK.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and/or individually, for a sum of money in excess of $100,000.00 as compensatory damages, punitive damages, attorneys fees, interest, costs, and other such relief as the Court may deem to be necessary, in the interest of justice.

THIRD COUNT – [PUNITIVE DAMAGES]

35. Plaintiff hereby incorporates all of the above paragraphs as if each were set forth in full herein.

36. Defendants actions were intentional, wanton, willful, and outrageous.

37. Defendants were grossly negligent and acted with reckless disregard and with deliberate callous and reckless indifference to the rights, interest, welfare and safety of the Plaintiffs.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and/or individually, for a sum of money in excess of $100,000.00 as compensatory damages, punitive damages, attorneys fees, interest, costs, and other such relief as the Court may deem to be necessary, in the interest of justice.

FOURTH COUNT [PRODUCTS LIABILITY]

38. Plaintiff hereby incorporates all of the above paragraphs as if each were set forth in full herein.

39. Defendants are liable under a theory of products liability when it knowingly permitted a defective product to enter the stream of commerce.

40. Defendant caused injury to the plaintiff and did so by failing to properly design, manufacture, produce, assemble, service, maintain, distribute, deliver and sell and supply the product in a defective condition, design and manufacture, produce, assemble, service, maintain, distribute and deliver a product which was unreasonably dangerous to the user, not safe for normal handling and consumption, failed to have adequate warning, failed to provide a proper instruction, failed to warn the user of the dangers of use of said product; failed to instruct the user in the use of said product, and failed to design a product which could have been designed more safely and failed to take all necessary steps to protect the user of said product; as a result the defendants manufactured and distributed a dangerous product and the Plaintiff was caused to experience great pain and suffering, continues to experience great pain and suffering, and ultimately caused the death of plaintiff, STEPHEN A. SUK.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and/or individually, for a sum of money in excess of $100,000.00 as compensatory damages, punitive damages, attorneys fees, interest, costs, and other such relief as the Court may deem to be necessary, in the interest of justice.

FIFTH COUNT [MEDICAL MALPRACTICE]

41. Plaintiff hereby incorporates all of the above paragraphs as if each were set forth in full herein.

42. Defendants, unidentified treating doctors, physicians, nurses and medical staff ("medical personnel"), plead as John Doe's 1-10, are liable for medical malpractice.

43. Defendants, physicians and medical personnel, owed a duty of care to the decedent to administer the vaccine with the requisite caution and care so as not to cause serious bodily harm and death.

44. Defendants breached this duty of care when they administered the vaccine to an otherwise healthy young man and he was caused to endure significant bodily harm and ultimately death.

45. Even if the death of the decedent was caused by strange and unusual circumstances, the treating medical personnel had a duty, at the very least, to conduct routine blood tests and other regular and routine tests which would have revealed the decedent's particular susceptibility to the vaccine used, and the medical personnel had a duty to warn the decedent of the inherent dangers of this mandatory vaccination procedure.

46. The medical personnel breached this duty to administer the drug with the requisite care, to warn the decedent of the potential hazards of this vaccine and to advise the

decedent of his particular susceptibility, and as a result of this gross negligence the decedent died.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and/or individually, for a sum of money in excess of $100,000.00 as compensatory damages, punitive damages, attorneys fees, interest, costs, and other such relief as the Court may deem to be necessary, in the interest of justice.

SIXTH COUNT [WRONGFUL DEATH]

47. Plaintiff hereby incorporates all of the above paragraphs as if each were set forth in full herein.

48. Decedent was caused severe bodily harm, emotional and mental distress and death as a result of the reckless, willful and wanton actions of the defendants.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and/or individually, for a sum of money in excess of $100,000.00 as compensatory damages, punitive damages, attorneys fees, interest, costs, and other such relief as the Court may deem to be necessary, in the interest of justice.

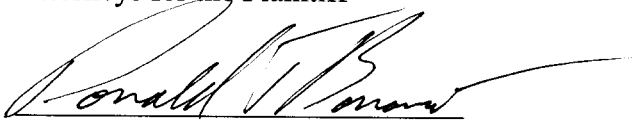
SEVENTH COUNT – [LOSS OF CONSORTIUM]

49. Plaintiff hereby incorporates all of the above paragraphs as if each were set forth in full herein.

50. As a result of the injuries sustained by the Plaintiff, the spouse of the Plaintiff has been deprived of the assistance, companionship, consortium and society of their spouses, all to their loss and detriment.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and/or individually, for a sum of money in excess of $100,000.00 as compensatory damages, punitive damages, attorneys fees, interest, costs, and other such relief as the Court may deem to be necessary, in the interest of justice.

KIM & ASSOCIATES, P.C.
Attorneys for the Plaintiff

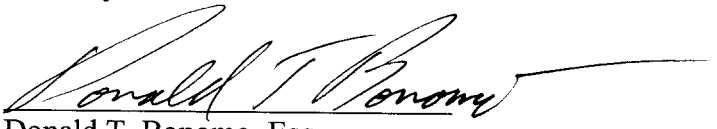
By: 
Donald T. Bonomo, Esq.

Dated: May 30, 2003

DEMAND FOR A TRIAL BY JURY

The Plaintiff hereby respectfully request and demands a trial by jury as to all issues so triable.

KIM & ASSOCIATES, P.C.
Attorneys for the Plaintiff

By: 
Donald T. Bonomo, Esq.

Dated: May 30, 2003

STATEMENT OF PENDING CONTROVERSIES

I hereby declare and certify that there are no other pending civil actions or arbitrations arising out of the transactions or series of transactions that are the subject matter of this complaint, and that no other ones are pending. I also declare and certify that there are no other parties who should be joined with this action.

KIM & ASSOCIATES, P.C.
Attorneys for the Plaintiff

By: 
Donald T. Bonomo, Esq.

Dated: May 30, 2003